# Million Hearts Risk Check Challenge - Fact Sheet

### Timeline

Submission Period Deadline: October 31

Review Period: November 2-13 Finalists Notified: November 19

Testing Period: November 19-December 31 Winner Announcement: January, 2013

# **Utilization Reporting Requirements**

Finalists and grand prize winner may be asked to report usage statistics to HHS on a regular basis. These statistics may include:

- Number of downloads (by city, if possible)
- Number of users that complete first eight questions of risk assessment
- Number of users that complete lipid and blood pressure questions of risk assessment
- Numbers of users

# **Data Privacy and Security**

The Million Hearts Risk Check Challenge does not have specific data privacy and security provisions or requirements. Unless solvers are a health care provider, health plan, or health care clearinghouse, they are not a "covered entity" to which the HIPAA Privacy and Security Rules apply (visit <a href="http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html">http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html</a> for more information on covered entities). It is up to the solver to choose and implement appropriate data security measures.

## **FDA**

Submissions are likely to fall under the category of "clinical decision support software" (CDDS). While policy in this area is not yet fully developed, claims to general health and wellness are likely to be sufficiently low-risk as to avoid the requirement of pre-market notification or approval.

### **Flat Files**

Flat files of blood pressure and/or lipid screening locations will be maintained by HHS and updated regularly with new locations. Flat files will resemble the attached (See Appendix E) and will be accessible to app developers via the web (most likely at the following location via Google Docs: <a href="https://docs.google.com/spreadsheet/ccc?key=0Ava71fiLGwS0dDZxTEp3WklzZkN4dnRnUkotSDhZU3c#gid=1">https://docs.google.com/spreadsheet/ccc?key=0Ava71fiLGwS0dDZxTEp3WklzZkN4dnRnUkotSDhZU3c#gid=1</a>).

Please note – flat files may contain locations that have only blood pressure screening, or only lipid screening (i.e., locations that do not offer BOTH services). Apps are expected to accommodate these locations.

## Archimedes API

Archimedes has made some modifications to their API, which have been included as tracked changes in Appendix A and Appendix B. Please review the modifications before submitting your application. The Archimedes API will function with real algorithms and results by November 19.